510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K043208

B. Purpose for Submission:

Reason for submission: formulation change – addition of one analyte.

C. Measurand:

Lactic acid has been added to this pre-existing quality control serum (see below). .

D. Type of Test:

Quality Control Material

E. Applicant:

Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, California 92618

F. Proprietary and Established Names:

Liquid Assayed Multiqual 1
Liquid Assayed Multiqual 2
Liquid Assayed Multiqual 3
Liquid Assayed Multiqual MiniPak

G. Regulatory Information:

1. Regulation section:

   21CFR862.1660 - Quality control material (assayed and unassayed).

2. Classification:
   Class I (reserved)

3. Product code:
   JJY

4. Panel:

   (75)Chemistry

H. Intended Use:

1. Intended use(s):

   Liquid Assayed Multiqual is intended for use as an assayed quality control serum to monitor the performance of laboratory testing procedures for the analytes listed in the package insert.

2. Indication(s) for use:

   Liquid Assayed Multiqual is intended for use as an assayed quality control serum to monitor the performance of laboratory testing procedures for the analytes listed in this package insert.

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   Varies with test instrument.

I. Device Description:

Liquid Assayed Multiqual is prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added. The product is provided as a liquid.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Liquid Assayed Multiqual

2. Predicate 510(k) number(s):

   K011867

3. Comparison with predicate:

   The currently marketed device is similar in analyte composition and concentrations to the predicate device with the exception of the addition of Lactic acid.

K. Standard/Guidance Document Referenced (if applicable):

None

L. Test Principle:

The product under submission is used by technicians to confirm the performance of lab or clinical instruments. The specific test varies with the instrument verified.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not Applicable
   b. *Linearity/assay reportable range:*
      Not Applicable
   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

      Expected Values

      Liquid Assayed Multiqual is prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added.

      Analysis by the manufacturer of the test kit or instrument used:
      In this case the manufacturer develops the target values. Whenever possible, Bio-Rad prefers to have the values assign in the way
      Analysis by reference laboratory:
      In this case, Bio-Rad contracts with reference laboratories for data generation. Three laboratories are used for each method listed in order to generate representative values.

      Stability

      The stability of the component analytes are the primary criteria for acceptance. Stability is measured by:

      - Open vial aging which mimics handling by the users of the product. These studies involve verifying concentration of the analytes when the product is stored capped but unsealed at 2 ºC to 8 ºC.
      - Accelerated Stability Testing which involves storing tested samples at elevated temperatures in an effort to predict their long-term performance.

      Test data provided by the manufacturer indicates that the predicate and pre-market device show similar, limited degradation of analytes as a function of time. The change in analyte concentrations is within the limits specified by the product inserts.

d. Detection limit:
Not Applicable

e. Analytical specificity:
Not Applicable

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   Not Applicable
   b. Matrix comparison:
   Not Applicable
3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
   c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:
   Not Applicable
5. Expected values/Reference range:
   Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.